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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,049	09/12/2003	Richard D. Cummings	7148.003	7472

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EXAMINER	
RAMIREZ, DELIA M	
ART UNIT	PAPER NUMBER
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,049	CUMMINGS ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,18 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-18,24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 17-18, 24-26 are pending.

Applicant's amendment of claims 17-18, 24 as submitted in a communication filed on 11/3/2006 is acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

1. Claim 18 is objected to due to the recitation of "recombinent". This appears to be a typographical error. It should be amended to recite "recombinant". Appropriate correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 17-18 and 24-26 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection has been discussed at length in the previous Office actions and it is maintained for the reasons of record and those set forth below.

4. Applicant argues that the claims have been amended such that the indicate that the cell is isolated, the core 1 β 3-galactosyltransferase requires coexpression of a core 1 β 3-galactosyltransferase specific chaperone for obtaining an active core 1 β 3-galactosyltransferase, and the hybridization conditions are now high stringency conditions. Thus, the claimed invention is adequately described and enabled.

5. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the instant rejection. The Examiner acknowledges the amendments to the specification. However, the claims still require a genus of polynucleotides encoding core 1 β 3-galactosyltransferases having any structure, wherein said core 1 β 3-galactosyltransferases are activated by either (1) the polypeptide of SEQ ID NO: 1, or (2) structural homologs of the polypeptide of SEQ ID NO: 1 encoded by nucleic acids which hybridize to the polynucleotide of SEQ ID NO: 2 under the conditions recited. While it is agreed that the claims requires that the core 1 β 3-galactosyltransferase be activated by the recited chaperones, the specification and the art are completely silent with regard to the structural elements required in any core 1 β 3-galactosyltransferase such that it can be activated by the chaperone of SEQ ID NO: 1 or structural homologs of said chaperone. Furthermore, neither the specification, nor the art provide any information as to the structural elements within the only human core 1 β 3-galactosyltransferase disclosed in the specification (pages 50-54) required in any core 1 β 3-galactosyltransferase that can be activated by the chaperone of SEQ ID NO: 1. With regard to the structural homologs of the chaperone of SEQ ID NO: 1, the specification and the art are completely silent with regard to the structural features of any core 1 β 3-galactosyltransferase which can be activated by these homologs. There is not a single species disclosed of a core 1 β 3-galactosyltransferase which can be activated by the recited homologs. In fact, there is not even any disclosure as to whether the only human core 1 β 3-galactosyltransferase disclosed in the specification can be activated by the recited homologs of the chaperone of SEQ ID NO: 1. As indicated in previous Office actions, the art teaches that even small structural variations can have a significant impact on function. In the absence of some structure/function correlation which would allow one of skill in the art to recognize which core 1 β 3-galactosyltransferases are going to be activated by the chaperone of SEQ ID NO: 1, or a structural homolog of the chaperone of SEQ ID NO: 1, one cannot reasonably conclude that the genus of nucleic acids encoding core 1 β 3-galactosyltransferases as recited in the claims is adequately described.

6. Claims 17-18 and 24-26 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an expression system comprising an isolated recombinant host cell comprising a polynucleotide encoding the polypeptide of SEQ ID NO: 1 and a polynucleotide encoding the human core 1 β 3-galactosyltransferase as described in pages 50-54 of the specification, does not reasonably provide enablement for an expression system comprising (1) a nucleic acid which encodes any core 1 β3-galactosyltransferase activated by (i) the chaperone of SEQ ID NO: 1, or (ii) structural homologs of the chaperone of SEQ ID NO: 1, and (2) a nucleic acid which hybridizes under the conditions recited to the polynucleotide of SEQ ID NO: 2 and encodes a protein which would activate any core 1 β 3-galactosyltransferase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection has been discussed at length in the previous Office actions and it is maintained for the reasons of record and those set forth below.

7. Applicant's arguments regarding this rejection are those previously summarized above regarding the written description rejection.

8. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the instant rejection. The Examiner acknowledges the amendments made to the claims. However, the Examiner disagrees with Applicant's contention that the claimed invention is enabled by the teachings of the specification. With regard to the genus of nucleic acids encoding the chaperone homologs, using the equation of Meinkoth and Wahl cited in the previous Office action, Tm = 81.5 °C +16.6x$\log_{10}$[Na+] +0.41x(%GC) - .61x(%form) – 500/L, the corresponding Tm for the polynucleotide recited in claim 17(b) at 0.1xSSC at 50 °C is approximately 73°C assuming a G+C content of 50% (73 °C = 81.5 + 16.6x$\log_{10}$[3.9/200] +0.41x(%50) - 500/957 (L= 957 nucleotides; for 20xSSC the molar concentration of Na+ is 3.9). As known in the art, Tm is reduced by approximately 1 °C for each 1% mismatching,

therefore under the conditions recited (0.1xSSC and 55 °C), a wash at 55 °C is equivalent to approximately 23% mismatching (23% = 73°C – 50 °C). This level of mismatching amounts to 221 nucleotides which can be modified (221 = 0.23x957) within SEQ ID NO: 2. A similar calculation with the alternative conditions recited (65 °C, 2xSSC), the Tm for the polynucleotide of claim 17(b) is approximately 95 °C. Thus a wash at 65 °C is equivalent to approximately 30% mismatching (30% = 95°C – 65 °C), which amounts to 288 nucleotides which can be modified (288 = 0.3x957) within SEQ ID NO: 2. The genus of polynucleotides recited can potentially encompass polynucleotides encoding proteins which are 9.5% - 30.5% sequence identical to the polypeptide of SEQ ID NO: 1 since the 221/288 mismatches can potentially alter 221/288 codons (9.5% = 100% -288x100/318; 30.5% = 100% - 221x100/318). The specification is completely silent with regard to (1) the structural elements required in any nucleic acid encoding the recited chaperone homologs, or (2) a structure/function correlation which would allow one of skill in the art to select a reasonable number of species more likely to have the same chaperone function as that of the polypeptide of SEQ ID NO: 1 for testing. Thus, one of skill in the art would have to test an enormously large number of nucleic acids to determine which ones have the same chaperone activity as that of the polypeptide of SEQ ID NO: 1.

With regard to the genus of nucleic acids encoding core 1 β 3-galactosyltransferases, as indicated above, neither the specification nor the art provide any clue as to the structural elements required in any core 1 β 3-galactosyltransferase as recited that can be activated by the chaperone of SEQ ID NO: 1 or homologs thereof. Thus, one of skill in the art would have to go through the burden of undue experimentation to identify (1) which core 1 β 3-galactosyltransferases can be activated by the chaperone of SEQ ID NO: 1, and (2) which core 1 β 3-galactosyltransferases can be activated by the structural homologs of the chaperone of SEQ ID NO: 1 recited in the claims. In view of the teachings of the specification and the art, and the state of the art regarding the unpredictability of assigning function based

solely on structural homology, one of skill in the art cannot reasonably conclude that the claimed invention is fully enabled by the teachings of the specification.

Claim Rejections - 35 USC § 102

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 17-18 and claim 24 were rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (WO 00/15796 published on March 23, 2000). This rejection has been discussed at length in the previous Office action. It is noted that due to a typographical error, claim 25 was listed as one of the claims rejected on the first line of the rejection. However, the intended claim was claim 24, as clearly stated in the text of the rejection.

11. Applicant argues that the claims as amended now require that both expressible nucleic acids be recombinant. Since Chen et al. do not teach a recombinant core 1 β3-galactosyltransferase in the 293 cell, nor would there be a motivation to introduce a cDNA encoding a recombinant core 1 β3-galactosyltransferase in the 293 cell, this reference does not anticipate or render obvious the claimed invention. Applicant also points out that the citation in Chen et al. describing endogenous production of core 1 β3-galactosyltransferase in 293 cells could not be found.

12. With regard to the endogenous production of core 1 β3-galactosyltransferase in 293 cells, it is noted that the Examiner did not indicate a particular page in the reference of Chen et al. because, as indicated in the previous rejection, the production of endogenous production of core 1 β3-galactosyltransferase in 293 cells was taught by Applicant in the specification (page 51, lines 4-5). Thus, the endogenous production of β3-galactosyltransferase in 293 cells, while not specifically taught by Chen et al., was evidenced by the teachings of the specification.

13. In view of Applicant's amendment of the claims, which now require a recombinant polynucleotide encoding a core 1 β3-galactosyltransferase, and the teachings of Chen et al., which do not teach or suggest expression of a recombinant polynucleotide encoding a core 1 β3-galactosyltransferase, this rejection is hereby withdrawn.

Conclusion

14. No claim is in condition for allowance.

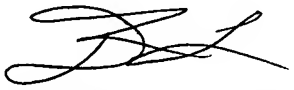
15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally

be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
January 10, 2007